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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,789	11/08/2000	Samsun Lampotang	UF-246XC1	2465

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EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/31/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/708,789	LAMPOTANG ET AL.
Examiner	Art Unit	
LaToya L. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 May 2003.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-28, 31 and 37 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-28, 31 and 37 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

This Office Action is in response to Applicants' amendment filed on May 14, 2003 and entered as Paper No. 8. Claims 1-28, 31 and 37 are pending. In the papers filed, there is an incorrect serial number on the cover page (09/708,537). Applicants should make sure that the serial number on all future correspondence is correct to assure that papers are matched with the correct file in a timely fashion.

### ***Withdrawal of Rejections from Previous Office Action***

- The rejection of claims 1-3, 9-11, 15, 28, 31, 37 and 38 under 35 USC 102(e) over Ayer et al is withdrawn in view of Applicants' amendment to claims to recite that the patient compliance of medicine taken volitional is determined. Likewise, the rejection of claims 6 and 12-14 under 35 USC 103 over Ayer et al in view of Greenberg et al and the rejection of claims 4, 5, 7, 8, 16, 17, 21-25, 29 and 30 under 35 USC 103 are both withdrawn for the same reason.
- The rejection of claims 32-36 under 35 USC 102(e) over Shinar et al is withdrawn in view of Applicant's cancellation of the claims.

### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-3, 9-11, 15, 18-20, 26-28, 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kell in view of Ayer et al.

Kell is directed to monitoring therapeutic agent consumption by using markers in combination with therapeutic agents. Kell discloses monitoring patient compliance with medication prescriptions by associating a compliance marker with the drug to be taken by the patient. The medication containing a compliance marker is ingested by the patient (volitional action as recited in claims 1 and 31). After ingestion, a sample of the patient's urine is collected and tested for the presence of the marker. As a part of the monitoring method, Kell teaches measuring the concentration of marker and comparing that with an expected (predetermined) marker as an indication of the consumption of the therapeutic agent, as recited in claims 18-20, 26 and 27.

Kell differs from the instantly claimed invention in that the method of Kell involves monitoring patient compliance by testing urine from the patient, whereas the instant invention tests breath samples from the patient.

Ayer et al teach a method for monitoring the deliverance of a medication into a patient's body. The method comprises providing a detectable marker in combination with a beneficial agent. The detectable marker is one that can be detected non-invasively, such as those detectable in the patient's breath (col. 5, lines 45-47). As exemplary markers, Ayers et al teach dimethylsulfoxide which emits an odor detectable with a sulfur detector. The beneficial agent is a drug used to treat disease or other pathological conditions (col. 7, line 3-6). The reference teaches that a drug is delivered into the patient's body. Subsequently, the marker is vaporized and detected in the patient's expelled breath (col. 8, lines 36-39).

It would have been obvious to one of ordinary skill in the art to determine patient compliance in taking medication by testing expelled breath, as opposed to urine. Kell discusses the need for monitoring patient compliance in non-invasive manners. One of ordinary skill in

the art would have been motivated to test expelled breath because it would be harmless, safe and non-invasive. Furthermore, in testing expelled breath, as opposed to urine, it is less likely that the sample will be adulterated by patient. Thus, more accurate results are provided.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Kell and Ayer et al.

3. Claims 6 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kell and Ayer et al as applied to claims 1-3, 9-11, 15, 18-20, 26-28, 31 and 37 above, and further in view of Greenberg et al.

With respect to claim 6, neither Kell nor Ayer et al teach the particular markers recited. With respect to claims 12-14, neither Kell nor Ayer et al teach the particular manners for introducing the drugs into the body.

Greenberg et al teach that flavorants are conventionally added to drugs as sweeteners and flavor enhancers. Greenberg et al teach that cinnamaldehydes, citrus oils, fruit essences, etc can be added to drugs (col. 5, lines 21-37 and col. 9, lines 24-31). It would have been obvious to add flavorants to the drugs of Ayer et al because, like the dimethylsulfoxide taught by Ayer et al, most flavorants have a distinctive scent that would be able to be detected in the breath of the patient. Flavorants also add a pleasant taste to the drugs to increase the chances that the patient will actually take the drugs.

With respect to claims 12-14, Applicants' recited manners for delivering the medicine are known and conventionally used in the art of medications. It would have been obvious to one of ordinary skill in the art to deliver the medication of Ayer et al in any manner that is suitable and easiest to use.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Kell in view of Ayer et al and Greenberg et al.

4. Claims 4, 5, 7, 8, 16, 17 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kell and Ayer et al as applied to claims 1-3, 9-11, 15, 18-20, 26-28, 31 and 37 above, and further in view of Shinar et al, Katzman et al, Tamada and Kenny et al.

With respect to claims 4, 5, 7, 8, 16, 17 and 21-25, Applicants recite several breath analysis instruments. While Ayer et al teaches using breath tests to analyze a patient's breath for the detection of compliance markers, no particular instruments are taught.

However, the analyzers recited by Applicants in claims 4, 5, 7, 8, 29 and 30 are conventionally used in the art to detect substances in gases and/or air. Shinar et al teach using SAW devices to determine analytes in gases. Katzman et al teach using mass spectrometers; Tamada teaches transdermal detection and Kenny et al teach using spectrophotometers. Each of the devices contains means for collecting data and further means for outputting the data to the user.

It would have been obvious to one of ordinary skill in the art to use any known measuring device to detect the markers of Ayer et al. Those recited by Applicants are known to be suitable in gas analysis and would provide an effective means for determining the presence of markers in breath samples and providing output for the user to determine the results of the analysis.

***Response to Arguments***

5. Applicant's arguments with respect to claims 1-28, 31 and 37 have been considered but are moot in view of the new ground(s) of rejection.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Art Unit: 1743

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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July 28, 2003

  
Jill Warden  
**Supervisory Patent Examiner**  
**Technology Center 1700**